

PRIA Fee Category Table – Antimicrobials Division – Experimental Use Permits and Other Actions

Table 10.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-experimental-use-permits-and-other-actions" \l "footnote1"]	FY'17 & FY'18 Registrati on Service Fee (\$)
[HYPERLINK "http://www2.epa.gov/pria-fees/a520-pria-fee-category"]	94	Experimental Use Permit application, non-food use [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-experimental-use-permits-and-other-actions" \l "footnote2"]	9	6,383
[HYPERLINK "http://www2.epa.gov/pria-fees/a521-pria-fee-category"]	95	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 1	4	4,726
[HYPERLINK "http://www2.epa.gov/	96	Review of public health efficacy study protocol outside AD	12	12,156

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pria-fees/a522-pria-fee-category"]		by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 2		
A537	97 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows.	18	153,156
A538	98 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows.	18	95,724
A539	99 (new)	New Active Ingredient/New Use, Experimental Use	15	92,163

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		Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows.		
[HYPERLINK "http://www2.epa.gov/pria-fees/a529-pria-fee-category"]	100	Amendment to Experimental Use Permit; requires data review or risk assessment [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-experimental-use-permits-and-other-actions" \l "footnote2"]	9	11,429
[HYPERLINK "http://www2.epa.gov/pria-fees/a523-pria-fee-category"]	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols)	9	12,156
[HYPERLINK "http://www2.epa.gov/pria-fees/a571-pria-fee-category"]	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated.	18	95,724
A533	103 (new)	Exemption from the requirement of an Experimental Use Permit [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-	4	2,482

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		antimicrobial-division-experimental-use-permits-and-other-actions" \l "footnote2"]		
A534	104 (new)	Rebuttal of agency reviewed protocol, applicant initiated	4	4,726
A535	105 (new)	Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated	6	2,409
A536	106 (new)	Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated	4	2,482

¹A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

²Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a),

including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.